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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/581,144

07/05/2007

Christian Belmant

INN-135

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SALIWANCHIK LLOYD & SALIWANCHIK  
A PROFESSIONAL ASSOCIATION  
PO BOX 142950  
GAINESVILLE, FL 32614-2950

EXAMINER

LAU, JONATHAN S

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

09/22/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/581,144	<b>Applicant(s)</b> BELMANT ET AL.	
	<b>Examiner</b> Jonathan S. Lau	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 23-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 23-35 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

This Office Action details a Restriction Requirement and two Election of Species Requirements.

### **REQUIREMENT FOR UNITY OF INVENTION**

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

#### **When Claims Are Directed to Multiple Categories of Inventions:**

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1)A product and a process specially adapted for the manufacture of said product; or

(2)A product and process of use of said product; or

(3)A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4)A process and an apparatus or means specifically designed for carrying out the said process; or

(5)A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

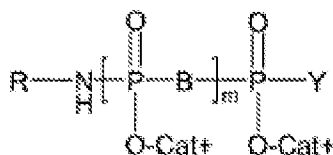
### ***Restriction Requirement***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 23-26 in part, drawn to a composition comprising a compound



according to general Formula (I) wherein Y is a radical selected from the group consisting of a nucleoside, and oligonucleotide and a nucleic acid. (see Examiner's note)

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Group II, claim(s) 23-26 in part, drawn to a composition comprising a compound according to general Formula (I) wherein Y is a radical selected from the group consisting of an amino acid, a peptide and a protein. (see Examiner's note)

Group III, claim(s) 23-26 in part, drawn to a composition comprising a compound according to general Formula (I) wherein Y is a radical selected from the group consisting of a monosaccharide, an oligosaccharide and a polysaccharide. (see Examiner's note)

Group IV, claim(s) 23-26 in part, drawn to a composition comprising a compound according to general Formula (I) wherein Y is a radical selected from the group consisting of a folic acid and a tetrahydrofolic acid. (see Examiner's note)

Group V, claim(s) 23-26 in part, drawn to a composition comprising a compound according to general Formula (I) wherein Y is a selected from the group consisting of O<sup>-</sup> Cat<sup>+</sup>, a C<sub>1</sub>-C<sub>3</sub> alkyl group, a group -A-R, a fatty acid, a simple lipid, a complex lipid, a phosphoric acid, an inositol, a flavonoid, an aldehyde, an epoxide and a halohydrin. (see Examiner's note)

Group VI, claim(s) 27-29, drawn to a method of making a diphosphoramidate monoester compound.

Group VII, claim(s) 30, drawn to a method of making a (E)-2-(4-azido-2-methylbut-2-enyloxy)tetrahydro-2H-pyran compound.

Group VIII, claim(s) 31-35 in part, drawn to a method of activating T cells or stimulating an immune response comprising administering a composition comprising a compound according to general Formula (I) wherein Y is a radical selected from the group consisting of a nucleoside, and oligonucleotide and a nucleic acid. (see Examiner's note)

Group IX, claim(s) 31-35 in part, drawn to a method of activating T cells or stimulating an immune response comprising administering a composition comprising a compound according to general Formula (I) wherein Y is a radical selected from the group consisting of an amino acid, a peptide and a protein. (see Examiner's note)

Group X, claim(s) 31-35 in part, drawn to a method of activating T cells or stimulating an immune response comprising administering a composition comprising a compound according to general Formula (I) wherein Y is a radical selected from the group consisting of a monosaccharide, an oligosaccharide and a polysaccharide. (see Examiner's note)

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Group XI, claim(s) 31-35 in part, drawn to a method of activating T cells or stimulating an immune response comprising administering a composition comprising a compound according to general Formula (I) wherein Y is a radical selected from the group consisting of folic acid and a tetrahydrofolic acid. (see Examiner's note)

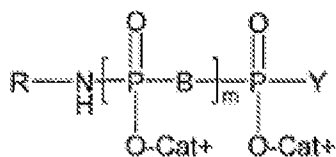
Group XII, claim(s) 31-35 in part, drawn to a method of activating T cells or stimulating an immune response comprising administering a composition comprising a compound according to general Formula (I) wherein Y is a radical selected from the group consisting of  $\text{O}^-\text{Cat}^+$ , a  $\text{C}_1\text{-C}_3$  alkyl group, a group  $-\text{A-R}$ , a fatty acid, a simple lipid, a complex lipid, a phosphoric acid, an inositol, a flavonoid, an aldehyde, an epoxide and a halohydrin. (see Examiner's note)

Examiner's note:

Claims 23, 31 and 33 recite "a vitamin" or "a co-enzyme", however, these terms do not convey any structural information, as vitamins and co-enzymes are classified by their biological and chemical activity, not their structure. These compounds will be grouped according to the structural group it corresponds to, for example a nucleoside (Group I), peptide (Group II), oligosaccharide (Group III), or a  $\text{C}_1\text{-C}_3$  alkyl group, a group  $-\text{A-R}$ , a fatty acid, a simple lipid, a complex lipid, a phosphoric acid, an inositol, a flavonoid, an aldehyde, an epoxide and a halohydrin (Group V).

The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups I-V and VIII-XIII lack unity of invention because even though the inventions of these groups require the technical feature of a compound of general

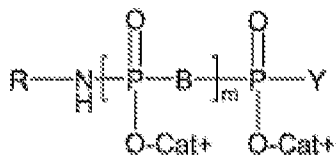


Formula (I)

, this technical feature is not a special technical

feature as it does not make a contribution over the prior art in view of Mustaev et al. (Proceedings of the National Academy of Sciences of the United States of America, 1994, 99, p12036-12040). Mustaev et al. discloses a compound Rif-C<sub>n</sub>-A (page 12037, figure 1A at bottom of page) as the lithium salt (page 12036, right column, paragraph *Rif-A compounds*). This compound meets the compound according to general Formula (I) where Y is a nucleoside and R is the combination of a hydrocarbon group, an amide, and an aryl group.

Groups VI, VII and I-V and VIII-XIII lack unity of invention because the groups do not share the same or corresponding technical feature. The technical feature of Group VI is a diphosphoramidate monoester compound. The technical feature of Group VII is a (E)-2-(4-azido-2-methylbut-2-enyloxy)tetrahydro-2H-pyran compound. The technical feature of Groups I-VI and VIII-XIII is a compound of general Formula (I)



Where a single claim defines alternatives of a Markush group, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in Rule 13.2, is considered met when the alternatives are of a similar nature. When the Markush grouping is for alternatives of chemical compounds, the alternatives are regarded as being of a similar nature where the following criteria are fulfilled:

(A) all alternatives have a common property or activity; AND

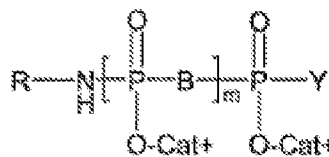
(B)(1) a common structure is present, that is, a significant structural element is shared by all of the alternatives; OR

(B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

The phrase “significant structural element is shared by all of the alternatives” refers to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity.

The phrase “recognized class of chemical compounds” means that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention, i.e. each member could be substituted one for the other, with the expectation that the same intended result would be achieved.

Although the chemical compounds of Groups I-V and VIII-XIII share a common



structure of a compound of general Formula (I), the common structure is not a significant structural element because it represents only a small portion of the compound structures and does not constitute a structurally distinc-



tive portion in view of Mustaev et al. (Proceedings of the National Academy of Sciences of the United States of America, 1994, 99, p12036-12040), which teaches the binding of the compound based on the corresponding group R and the group Y (page 12037, figure 1B at bottom of page). Further, the compounds of these groups do not belong to a recognized class of chemical compounds. For example a nucleoside (Group I), peptide (Group II), oligosaccharide (Group III), or a C<sub>1</sub>-C<sub>3</sub> alkyl group, a group -A-R, a fatty acid, a simple lipid, a complex lipid, a phosphoric acid, an inositol, a flavonoid, an aldehyde, an epoxide and a halohydrin (Group V) are recognized as distinct classes of chemical compounds.

### ***Election of Species Requirement***

If Applicant elects the invention of Group I-V, Applicant is required to elect from the following **first** Election of Species Requirement.

If Applicant elects the invention of Group VIII-XII, Applicant is required to elect from both of the following **first** and **second** Election of Species Requirements.

This application contains claims directed to more than one first species of compound and second species of disease of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

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Examples of **first** species of compound are, for example disclosed in the specification:

1a) (E)-4-hydroxy-3-methylbut-2-enyl pyrophosphoramidate (N-HDMAPP), disclosed on page 37, lines 25-30, and

1b) 2-(2-methyloxiran-2-yl)ethyl pyrophosphoramidate (N-EpoXPP), disclosed on page 42, lines 10-20.

Examples of **second** species of disease are, for example disclosed in the specification:

2a) a lung tumor, disclosed on page 29, line 25,

2b) Influenza virus, disclosed on page 29, line 35, and

2c) diabetes, disclosed on page 30, line 6.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim. Currently, the following claim(s) are generic:

Claims 23-26 and 31-35 are generic to the species of compound.

Claims 31-35 are generic to the species of disease.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during

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prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jonathan Lau  
Patent Examiner  
Art Unit 1623

/Shaojia Anna Jiang, Ph.D./  
Supervisory Patent Examiner  
Art Unit 1623